

EXHIBIT 64



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Telephone (973) 526-6061

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

November 30, 2006

Divya Patel, President and CEO
Actavis Totowa, LLC
101 East Main Street
Little Falls, New Jersey 07424

Dear Mr. Patel:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at your premises at 4 Taft Road, Totowa, New Jersey on October 24-25, 2006 by Douglas C. Kovacs of the U.S. Food and Drug Administration (FDA). This new procedure is applicable to EIRs for inspections completed on or after April 1, 1997. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

The Agency is working to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it reflects redaction's made by the Agency in accordance with FOIA and 21 C.F.R. Part 20. This, however, does not preclude you from requesting any additional information under FOIA.

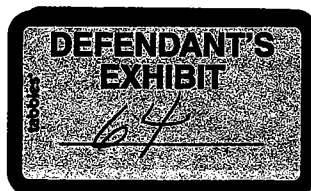
If there is any question about the released information, feel free to contact the undersigned.

Sincerely

Cary Greene
Supervisory Investigator

CG:gs

Enclosure



Establishment Inspection Report
 Actavis Totowa LLC
 Totowa, NJ 07512-1006

FEI: 3003450194
 EI Start: 10/24/2006
 EI End: 10/25/2006

TABLE OF CONTENTS

| | |
|---|---|
| SUMMARY | 1 |
| ADMINISTRATIVE DATA | 2 |
| HISTORY | 2 |
| INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED | 2 |
| FIELD ALERT REPORT/COMPLAINTS | 3 |
| REFUSALS | 4 |
| SAMPLES COLLECTED | 4 |
| EXHIBITS COLLECTED | 4 |
| ATTACHMENTS | 4 |

SUMMARY

Inspection of this drug packaging and testing facility was conducted as per FACTS Assignment 775191, Operation ID 3018456, a request to provide coverage to a Field Alert Report, dated 10/11/2006 concerning a possible product mix-up of two different strengths of [REDACTED]. The inspection was conducted in accordance to CP 7356.021 Drug Quality Reporting System-DQRS, NDA-Field Alert Reporting.

The previous inspection of 9/18-10/11/2006 covered the Quality, Packaging and Labeling, Laboratory Control, Facilities and Equipment and Materials Systems and was classified VAI. Deficiencies noted during the inspection included re-tested values were reported without invalidating original atypical/aberrant results, method validation studies were repeated without invalidating original results not meeting acceptance criteria and relating to cleaning validation issues concerning recovery studies and detergent residues.

The current inspection was limited to review of a Field Alert submitted on 10/11/2006 concerning a complaint received through FDA's DQRS reporting system that involved a product mix-up of two different strengths of [REDACTED]. The firm's investigation revealed that the same identical complaint was reported to the firm in March 2006 from a pharmacist in which the firm submitted a Field Alert Report to FDA in March 2006. In review of the firm's investigation, packaging records, cleaning and use logs and line set-up procedures and records, no deficiencies were noted. The firm's investigation concluded that the mix-up most likely occurred at the pharmacy.

No Form FDA 483, Inspectional Observations was issued, no samples were collected and no refusals were encountered.

Establishment Inspection Report

Actavis Totowa LLC
Totowa, NJ 07512-1006

FEI: 3003450194
EI Start: 10/24/2006
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ADMINISTRATIVE DATA

Inspected firm: Actavis Totowa LLC
Location: 4 Taft Rd
Totowa, NJ 07512-1006
Phone: (973) 890-1555
FAX:
Mailing address: 4 Taft Rd
Totowa, NJ 07512-1006

Dates of inspection: 10/24/2006, 10/25/2006
Days in the facility: 2
Participants: Douglas C. Kovacs, Investigator

On 10/24/2006, I displayed my credentials and issued Form FDA 482, Notice of Inspection and attachment "Resources for FDA Regulated Businesses" to Apurva Patel, Director, Project Management, who indicated that he was authorized to accept the notice in the absence of Divya Patel, President and CEO. Mr. Apurva Patel reports to Ashok G. Nigalaye, Senior Vice President, Scientific Affairs. I explained to Mr. Patel the purpose of the inspection was to conduct a follow-up to the Field Alert report concerning a product mix-up of two different strengths of [REDACTED]

Post-inspectional correspondence should be addressed to:
Divya Patel, President and CEO
Actavis Totowa LLC
101 East Main Street
Little Falls, New Jersey 07424

HISTORY

There were no changes to the company's history of business since the previous inspection of 9/18-10/11/2006.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

The following people were present during the inspection and provided information and copies of documents:

Establishment Inspection Report

Actavis Totowa LLC
Totowa, NJ 07512-1006

FEL: 3003450194
EI Start: 10/24/2006
EI End: 10/25/2006

- **Ashok G. Nigalaye, Ph.D., R.Ph., Senior Vice President, Scientific Affairs** was present on 10/24/2006 and provided information with regard to the firm's operations. Dr. Nigalaye reports to Divya Patel, President and CEO.
- **Jasmine Shah, R.Ph., Vice President Regulatory and Medical Affairs, US Products** was present on 10/25/2006 and provided product labeling and written procedures for reporting field alert reports. Mr. Shah reports to Ashok G. Nigalaye, Ph.D., R.Ph., Senior Vice President, Scientific Affairs.
- **Ashesh Dave, Director of Packaging and Labeling Operations**, was present on 10/24/2006, accompanied me during the walkthrough of the packaging and inspection areas, and provided information with regard to consumer complaints and investigations, use and clean logs, packaging records, and written procedures. Mr. Dave reports to Ashok G. Nigalaye, Ph.D., R.Ph., Senior Vice President, Scientific Affairs

FIELD ALERT REPORT/COMPLAINTS

[REDACTED] are manufactured in three Little Falls, New Jersey facility and subsequently transferred to the 4 Taft Road, Totowa, New Jersey site for packaging. Prior to packaging, the batch is inspected for gross defects such as illegible imprinting or sticking tablets.

On 10/11/2006 Actavis submitted a Field Alert Report concerning a complaint received through FDA's DQRS reporting system on 10/10/2006. The complaint (C06-140) involved a product mix-up of two different strengths of [REDACTED] in which a pharmacy technician observed triangular and oval shaped tablets in a bottle of [REDACTED]. The tablets were [REDACTED]. Ashesh Dave, Director of Packaging and Labeling Operations informed me that the firm also received the same identical complaint in March 2006, complaint C06-031 (Exhibit 1). Mr. Dave explained that they conducted an investigation for complaint C06-031 in 3/2006 and concluded that the mix-up did not occur at the facility (Exhibit 1). He stated that since complaint C06-031 and C06-014 were the same complaint, no additional investigations were conducted.

Mr. Dave provided the firm's investigation, use and clean logs for [REDACTED] and written procedures. My review of the use and clean logs for [REDACTED] revealed that with regard to [REDACTED], eight different lots/products were packaged between lot [REDACTED] and lot [REDACTED]. With regard to packaging [REDACTED], seven different lots/products were packaged between lot [REDACTED] and lot [REDACTED]. I reviewed the firm's procedures for inspecting the tablets and the clean and use logs for each room. I also reviewed the line clearance and QA approval documents for the inspection process of batches [REDACTED] and [REDACTED]. These two batches were inspected in different rooms in November 2005. I also conducted a walkthrough of the packaging areas and inspections rooms, and observed the finished product inspection process and packaging operations.

Establishment Inspection Report

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In addition, I reviewed complaints for product mix-up and noted that there were two additional complaints for [REDACTED] complaints C05-086 and C06-060 (Exhibits 2, 3). For each of these complaints, Field Alert Reports were submitted to FDA. The firm investigated each complaint and determined that the mix-up did not occur during manufacturing or packaging operations. In review of the packaging operations, written procedures and related documents, I did not observe any deficiencies.

Jasmine Shah, R.Ph., Vice President, Regulatory and Medical Affairs, US Products, explained that in an effort to prevent product mix-ups of different strengths of [REDACTED] at the pharmacies, the labels for each product are now color coded. Mr. Shah explained that the previous labels were very similar and provided examples of the previous labels for the three different strengths (Exhibit 4). Mr. Shah also provided the color coded labels for comparison (Exhibit 5).

REFUSALS

I did not encounter any refusals during the inspection.

SAMPLES COLLECTED

I did not collect any samples during the inspection.

EXHIBITS COLLECTED

1. Investigation for complaints C06-031 and C06-140 (20pp)
2. Investigation for complaint C05-086 (10pp)
3. Investigation for complaint C06-060 (10pp)
4. Labeling for [REDACTED] with Amide name (1p)
5. Labeling for [REDACTED] with Actavis name (1p)

ATTACHMENTS

- Hardcopy assignment (5pp)
- Form FDA 482, Notice of Inspection, dated 10/24/2006 (1p)

Establishment Inspection Report

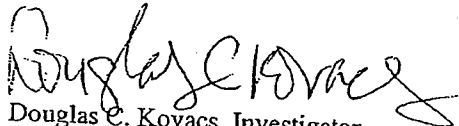
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Douglas E. Kovacs, Investigator